Section 5: 510(k) Summary

JUN - 2 2011

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
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Date Summary Prepared:	1 June 2011
Trade Name:	TAMPAX® C Plastic™ Tampons, unscented
Common Name:	Unscented Tampon
Classification Name:	Unscented menstrual tampon (21 CFR 884.5470)
Predicate Devices:	TAMPAX® Pearl Tampons, unscented K081555
Device Description:	Unscented menstrual tampons for absorption of menstrual fluid
Intended Use:	TAMPAX® C Plastic™ Tampons, unscented, are intended to be inserted into the vagina to absorb menstrual fluid

Technological Characteristics: The device is similar to the predicate devices in terms of basic component materials, overall design and labeling. The device is designed to acquire and hold menstrual fluids similar to the fluid handling capabilities of the predicate devices. A pigment has been added to the applicator, the applicator shape and the wrapper have been modified.

Nonclinical Testing: Tampon material safety and design have been established in 510(k) submission K081555. Extractions of the 510(k) device plastic applicators were performed under exaggerated conditions to confirm negligible or no tampon pledget exposure to the applicator components. Tests of the 510(k) tampon applicator expulsion force showed that the force is within acceptable limits. Tests of the seal strength (Thwing-Albert measurement) and peel strength (Instron measurement) of the 510(k) modified wrapper showed that the seal and peel strength of the wrapper is within specified limits. The results of these tests support the conclusion that the 510(k) device is equally as safe as the predicate devices.

Conclusions: The tampon pledget design was not changed from the predicate device. Extracts of the proposed and predicate device applicators show similar results. The modified applicator has similar expulsion force as the current applicator. The seal strength and peel strength results show that the modified wrapper has similar

integrity to the current wrapper. The results of the extraction testing and seal and peel strength testing for this device support the conclusion that it is safe for its intended use and is substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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JUN - 2 2011

Re: K110669
Trade Name: TAMPAX® C Plastic™ Tampons, unscented
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: May 3, 2011
Received: May 4, 2011

Dear Dr. Blieszner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K110669

Device Name TAMPAX® C Plastic™ Tampons, unscented

Indications for Use The TAMPAX® C Plastic™ Tampons, unscented, are intended to be inserted into the vagina to absorb menstrual fluid.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110669